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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,993	04/06/2006	E. Premkumar Reddy	35926032901US	2185
23973 7590 12/23/2008 DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996				
			EXAMINER	
			NWAONICHA, CHUKWUMA O	
		ART UNIT	PAPER NUMBER	
		1621		
		MAIL DATE	DELIVERY MODE	
		12/23/2008 PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/574,993

Applicant(s)

REDDY ET AL

Examiner

CHUKWUMA O. NWAONICHA

Art Unit

1621

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27, 32, 36, 37, 69 and 77 is/are pending in the application.
- 4a) Of the above claim(s) 28-31, 39 and 71-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 32, 36, 37, 69 and 77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Current Status

1. This action is responsive to Applicants' amendment of 4 September 2008.
2. Receipt and entry of Applicants' amendment is acknowledged.
3. Claims 1-27, 32, 36, 37, 69 and 77 are pending.
4. The 112 rejection is withdrawn following Applicants amendment.
5. The obviousness-type double patenting rejection of claims 1-27, 32, 36, 37, 69 and 77 as being unpatentable over claims 1-6, 8, 94, 95, 97-117, 122, 128 and 130-132 of the copending Application No. 10/592,604 in view of Singh et al. is maintain for the reason given in the previous Office Action 04/02/2008.

The rejection of claims 1-27, 32, 36, 37, 69 and 77 under 35 U.S.C. 103 as being unpatentable over Schwan et al., {1-Alkenesulfinyl Chlorides: Synthesis, Characterization, and Some Substitution Reactions, Journal of Organic Chemistry (1998), 63(22), 7825-7832} for the reasons set forth in the previous Office Action of 04/02/2008 is maintained.

Applicants' argument and amendments filed 4 September 2008 have been fully considered but they are not persuasive because Applicants claimed compound is obvious in view of the prior art references cited. Applicants' argument is based on methyl group versus hydrogen substitutions. Applicants claim the compound wherein the aryl ring is substituted with methyl group while the prior art teach compounds substituted with hydrogen. It should be noted that compounds that differ by methyl and hydrogen are expected to possess similar chemical and physical properties. Applicants

have failed to provide a side-by-side comparison of their methyl substituted compound and the hydrogen substituted compound prior arts in terms of their pharmaceutical activities. The submission of this data would make Applicants' argument convincing.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32, 36 and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for **"treating breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation with all the compounds of general formula I"** as claimed.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The standard for determining whether the specification meets the enablement requirement is whether experimentation needed to practice the invention is undue or unreasonable. Accordingly, even though the forgoing statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. See M.P.E.P. § 2164.

In the instant case, the claims cover **"treating breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation with all the compounds of general formula I"**. Based on the above standards, the disclosure must contained sufficient information to enable one skilled in the pertinent art to use this invention without undue experimentation. See M.P.E.P. 2164.01. Given the scope of the claims, it does not, because treating **"breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation with all the compounds of general formula I"** as claimed is speculative.

The Examiner understands that there is no requirement that the specification disclose every possible embodiment if there is sufficient guidance given by knowledge in the art (See M.P.E.P. § 2164.05(a)). However, the instant case goes beyond what is known in the art, because the specification does not offer any guidance on how one of ordinary skill would go about practicing the invention from the claim to treating **"breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation with all the compounds of general formula I"**.

Here, the requirement for enablement is not met since the claims go far beyond the enabling disclosure. Based on the forgoing, **claims 32, 36 and 37** are *prima facie* non-enabled for their full scope.

With regard to rejection under 35 U. S. C. 112, first paragraph, the following factors have been carefully considered (*In re Wands*, 8 USPQ2d 1400; CAFC, 1988):

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,

4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

(1) **Nature of the invention.** As indicated above, the invention is drawn to treating breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation. Specifically, Applicants claim treating the above diseases with **all compounds of general formula I**.

(2) **Breadth of the Claims.** The claims are extremely broad. In particular, **claims 32, 36 and 37** that read on specifically treating breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation with **all the compounds of general formula I**". Applicants have failed to exactly show how to treat "**breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation with all the compounds of general formula I**".

(3) **State of the Prior Art.** There is no known treatment of breast tumor, prostate tumor, lung tumor with all the compounds of general formula I as claimed. The prior arts teach Certain alpha,beta-unsaturated sulfones, particularly styrylbenzyl sulfones have been shown to posses antiproliferative, radioprotective and chemoprotective activity as disclosed in U.S. Pat. Nos. 6,599,932, 6,576,675, 6,548,553, 6,541,475, 6,486,210, 6,414,034, 6,359,013, 6,201,154, 6,656,973 and 6,762,207.

(4) **Unpredictability of the Art.** The instant case is drawn to treating breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation **all the compounds of general formula I**. Treating "breast tumor, prostate tumor, lung tumor

with all the compounds of general formula I" is speculative. Applicants' claim to **"treating breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation with all the compounds of general formula I"** is doubtful and requires objective proof. In such a speculative field, more enablement by way of specific examples is necessary in order to establish the utility of a genus. In re Fisher, 166 U.S.P.Q. 18.

(5) **Amount of Guidance Provided.** Applicants have not provided any guidance for using the claimed method to treating **"breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation with all the compounds of general formula I"**, it becomes critical to know how long does one administers the said compounds to treat the diseases. This is critical to the practice of the invention and therefore should adequately be disclosed.

(6) **Presence or Absence of Working Examples.** There are no examples of treating **"breast tumor, prostate tumor, lung tumor with all the compounds of general formula I"** disclosed. Applicants only disclose few examples showing the treatment of breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation with **few compounds**.

(7) **Ordinary Skill in the Art.** The ordinary skill artisan would not be able to practice the claimed invention with the current disclosure. This is a new field with no known success for the treatment of **"breast tumor, prostate tumor lung tumor, colorectal tumor and therapeutic ionizing radiation with all the compounds of general formula I"**.

(8) **Amount of Experimentation Necessary.** A great deal of experimentation is required. In lieu of the fact that no animal models exist which can reasonably suggest successful treating **"breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation with all the compounds of general formula I"**, it will be necessary for an ordinary skilled artisan to have clinical data in order to practice the claimed invention.

Thus, it can safely be concluded that the instant disclosure fails to provide an enabling disclosure for treating **"breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation with all the compounds of general formula I"** as claimed.

The Examiner suggests that Applicants limit the method of treatment claims to those compounds of general formula I that are enabling for treating breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is 571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chukwuma O. Nwaonicha/
Examiner, Art Unit 1621

/Jafar Parsa/

Primary Examiner, Art Unit 1621